Exhibit 61

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March 17, 2000

BY HAND DELIVERY

David Ogden, Esquire
Department of Justice
Main Justice Building
10th Street and Constitution Avenue, N.W.
Room 3744
Washington, DC 20530

Re: Analysis of Why the United States Should Decline Intervention in United States Ex Rel. [Relator] v. [Defendants] (S.D. Fla.) (Under Seal)

Dear Mr. Ogden:

On behalf of Dey, L.P.; ESI Lederle, Inc.; Fujisawa Healthcare, Inc.; Ben Venue Laboratories; SmithklineBeecham Pharmaceuticals; Novartis Pharmaceuticals Corporation; Baxter Healthcare Corporation; Immunex Corporation; Glaxo Wellcome, Inc.; Aventis Behring L.L.C. (Centeon); and Bristol Myers Squibb Company, I enclose an Analysis of Why the United States Should Decline Intervention in United States Ex Rel. [Relator] v. [Defendants] (S.D. Fla.) (Under Seal). After you have had an opportunity to review the Analysis, please let us know when we may schedule a meeting to discuss this matter further. I look forward to hearing from you.

Very truly yours,

David P. King

DPK:jvd

Enclosure

cc: Stuart Schiffer, Esq.
Michael Hertz, Esq.
T. Reed Stephens, Esq.

R1-014073

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Submitted on behalf of:

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Fujisawa Healthcare, Inc.
Ben Venue Laboratories
SmithklineBeecham Pharmaceuticals
Novartis Pharmaceuticals Corporation
Baxter Healthcare Corporation
Immunex Corporation
Glaxo Wellcome, Inc.
Aventis Behring L.L.C. (Centeon)
Bristol Myers Squibb Company

Dated: March 17, 2000

ANALYSIS OF WHY THE UNITED STATES SHOULD DECLINE INTERVENTION IN UNITED STATES EX REL. [RELATOR] V. [DEFENDANTS] (S.D. FLA.)(UNDER SEAL)

This Analysis, which sets forth the reasons why the United States should decline intervention in *United States ex rel. [Relator] v. [Defendants]* ("Analysis"), is submitted on behalf of the following Manufacturers: Dey, L.P., ESI Lederle, Inc., Fujisawa Healthcare, Inc., Ben Venue Laboratories, SmithklineBeecham Pharmaceuticals, Novartis Pharmaceuticals Corporation, Baxter Healthcare Corporation, Immunex Corporation, Glaxo Wellcome, Inc., Aventis Behring L.L.C: (Centeon), and Bristol Myers Squibb Company (collectively, the "Manufacturers"). 1/

INTRODUCTION

Just over two years ago, in a radio address to the nation regarding the Medicare system, President Clinton stated:

> *Sometimes the waste and abuse aren't even illegal; they're just embedded in the practices of the system.* Last week, the Department of Health and Human Services confirmed that our Medicare program has been systematically overpaying doctors and clinics for prescription drugs – overpayments that cost taxpayers hundreds of millions of dollars.... Now, these overpayments occur because Medicare reimburses doctors according to the published average wholesale price – the so-called sticker price – for drugs. Few doctors, however, actually pay the full sticker price. In fact, some pay just one tenth of the published price.

White House Office of Press Secretary, Remarks by the President in Radio Address to the Nation (Dec. 13, 1997)(emphasis added).

1/ This Analysis is presented pursuant to Fed. R. Evid. 408. Submission of this Analysis is not intended to waive, and does not waive, the attorney-client privilege, the attorney work product doctrine, or any other applicable evidentiary privilege or doctrine.

Nevertheless, the Department of Justice has alleged in our discussions that these "overpayments" *were* illegal. The Department contends that each of the Manufacturers "defrauded" the States and federal government by providing "inaccurate" pricing information for their drugs to certain commercial pricing services. As a result, the Department asserts, the Manufacturers "tricked" the government into paying "false" drug reimbursement claims. (The Department's peculiar definition of "false" in this case is "facially true but, in hindsight, the government paid more than the Department thinks it should have paid.")

This Analysis examines the factual evidence and legal principles that together demonstrate that the government's False Claims Act ("FCA") case is without merit. The President's statement identifies one of the principal reasons the Department of Justice cannot meet its burden in this case: federal and state government officials have long been aware that the "average wholesale price" ("AWP") is not the price at which providers purchase prescription drugs in a typical transaction.2/ Furthermore, federal and state officials also knew that "wholesale acquisition cost" ("WAC") was not intended to equate to provider acquisition cost.

Government knowledge negates any inference of wrongful intent and prevents the government from showing that it reasonably relied on the information

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2/ As the government has conceded, its case with respect to Medicare is particularly wanting because, in addition to the information discussed in this Analysis, the Medicare statute explicitly incorporates "AWP"-based reimbursement. *See, e.g.*, 42 U.S.C. § 1395u(o). This Analysis therefore focuses on the government's inability to prove a case based on claims submitted to Medicaid.

submitted. Wrongful intent and government reliance are essential elements of a "causes to be filed" FCA case such as this one. 3/

3/ To establish liability under section 31 U.S.C. § 3729(a)(1), the government must prove:

(1) The defendant presented or caused another person to present a "claim" for payment or approval to the United States;

(2) The claim was "false or fraudulent"; and

(3) The defendant acted "knowing" the claim was false or fraudulent.

United States ex rel. Stinson, Lyons, Gerlin & Bustamante v. Provident Life & Accident Ins. Co., 721 F. Supp. 1247, 1258-59 (S.D. Fla. 1989); *see* JOHN T. BOESE, CIVIL FALSE CLAIMS AND QUI TAM ACTIONS (1995 & Supp. 1999) § II.A [hereinafter BOESE].

Patently, none of the Manufacturers submitted "claims" to the United States, for § 3729(c) defines "claim":

> (c) **Claim defined.** – For purposes of this section, "claim" includes any request or demand, whether under a contract or otherwise, for money or property which is made to a contractor, grantee, or other recipient if the United States Government provides any portion of the money or property which is requested or demanded, or if the Government will reimburse such contractor, grantee, or other recipient for any portion of the money or property which is requested or demanded.

In providing information to the commercial pricing services, the Manufacturers did not make any request or demand for property or money, and their actions therefore do not fall within the scope of § 3729(c). Judicial interpretation is consistent with our conclusion. Courts and commentators have consistently recognized that statements or demands that result in no immediate financial detriment to the government are not "claims." *United States v. McNinch*, 356 U.S. 595 (1958) (no claim presented when government not required to pay any money or suffer immediate financial detriment); *see United States v. Niefert-White Co.*, 390 U.S. 228 (1968) ("claim" includes cases in which government has legal obligation to disburse the funds immediately and situations in which the government disburses funds without any legal obligation to do so). The Supreme Court has reiterated that a

Furthermore, "AWP" and "WAC" are not, as the Department of Justice today asserts, precisely defined terms. "AWP" has been widely understood to be a "sticker price;" "WAC" has been generally known to be an undiscounted wholesaler list price that does not reflect discounts, chargebacks, rebates, or special promotional prices to purchasers. Given that the these terms were widely and consistently understood *not* to reflect provider acquisition cost, the government will be unable to prove that the Manufacturers acted with the intent required by the FCA; that is, that they "knowingly" provided false information to the commercial pricing services or "knowingly" caused false claims to be submitted.

I. DISCUSSION

A. The Government Knew That "AWP" and "WAC" Did Not Approximate Provider Acquisition Cost

1. The December 1968 Report Identified Pricing Differentials

As early as 1968, the government had extensive knowledge of the issues that it claims to have "discovered" in this case. The report of the Task Force on Prescription Drugs of the Department of Health Education and Welfare ("HEW") entitled "The Drug Makers and the Drug Distributors" (Dec. 1968) pointed out that

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"claim" connotes "a demand for money or some transfer of public property." *United States v. Borstein*, 423 U.S. 303, 309 n.4 (1976) (quoting *McNinch*, 356 U.S. at 599).

In "causing [false claims] to be filed" cases, the government must prove that it justifiably relied on the information provided. *See, e.g., United States v. Data Translation, Inc.*, 984 F.2d 1256, 1259 (1st Cir. 1992) (Breyer, J.). Furthermore, the United States District Court for the Southern District of Florida has held that damages are an element of a § 3729(a)(1) claim. *Stinson*, 721 F. Supp. at 1258. The government's burden under § 3729(a)(2) is substantially similar. *See* BOESE, *supra*, at § II.A.2.

"wholesalers, retailers, hospitals and government agencies often pay markedly different prices for the same drug and dosage form." *Id.* at 31. The report expressly acknowledged: "The Red Book and the Blue Book do not reflect the actual manufacturers' prices to wholesalers and retailers . . . . The catalog [list] price constitutes an 'umbrella' beneath which the company can maneuver against competing products." *Id.* Thus, over 31 years ago, the government knew that "list prices" reported by the commercial pricing services were subject to discounts and other pricing differentials. *See also* 34 Fed. Reg. 1244, 1245 (Jan. 25, 1969)(HEW specifically notes that ingredient cost "may vary according to the size and location of the pharmacy and according to whether the dispensing is done by a physician").

2. Information Published During the 1970s Established That "Standard Prices" Exceeded Provider Acquisition Cost

During the 1970s, government reports showed that "AWP" *and* published prices *other than* "AWP" did not equate to provider acquisition cost. In November 1974, HEW published a proposal to establish limits on Medicaid payments for multiple source drugs, including drugs dispensed by physicians. The notice stated: "Red Book data, Blue Book data (i.e., AWP) *and other standard prices* . . . were frequently in excess of actual acquisition cost." 39 Fed. Reg. 41,480 (Nov. 27, 1974)(emphasis added); *see* 40 Fed. Reg. 34,516 (Aug. 16, 1975)(final rule). This published notice says more than that the government knew of the disparity between "AWP" and provider acquisition cost: it expressly states that "other standard prices" (such as "WAC") were *also* in excess of that cost.

HCFA reminded the States in a December 1977 Action Transmittal that they were required to estimate provider acquisition cost in setting reimbursement. HCFA criticized the states' use of "AWP" in implementing federal regulations, stating: "[T]he Department is not convinced that those states which continue to reimburse at average wholesale price *or wholesale invoice cost* have made a real effort to approach actual acquisition cost." "Title XIX Social Security Act: Limitation on Payment Reimbursement for Drugs: Estimated Acquisition Cost (EAC)," HCFA Action Transmittal 77-13 (MMB) (Dec. 13, 1977) (emphasis added), *reprinted in* Medicare & Medicaid Guide (CCH) ¶ 28,714.

Thus, by the end of the 1970s, the government had published a report, a Federal Register notice, and a HCFA transmittal recognizing that "AWP," "wholesale invoice cost," and "other standard prices" were in excess of provider acquisition cost. The next decade saw the publication of authoritative information explaining the size of the differential.

3. Information Published During the 1980s Identified the Size of the Differential Between Provider Acquisition Cost and "Standard Prices"

During the 1980s the government examined on repeated occasions the amount of the difference between provider acquisition cost and "AWP." The first two reports focused on retail pharmacies.

In 1980, the General Accounting Office reported that the Department of Health and Human Services ("HHS") was aware that "AWP" was typically 15%-18% higher than the price pharmacists actually paid for the drug. *See* GAO, "Programs to Control Prescription Drug Costs Under Medicaid and Medicare Could

be Strengthened," GAO Rep. No. HRD-81-36 (Dec. 31, 1980), *reprinted in* Medicare & Medicaid Guide (CCH) ¶ 30,907. Retail pharmacies have consistently acknowledged that they pay among the highest prices for pharmaceuticals, *see, e.g., In re Brand Name Prescription Drugs Antitrust Litigation*, 186 F.3d 781, 783, 786 (7th Cir. 1999), *cert. denied*, 2000 WL 198975 (U.S. Feb. 22, 2000), so the States could surely have deduced by 1980 that other providers were paying substantially less than even "AWP" minus 15%.

This message was unequivocally reiterated less than four years later. In 1984, the Office of the Inspector General ("OIG") of HHS reported that pharmacies purchased most drugs at an average of 15.9% below "AWP," "Changes to Medicaid Prescription Drug Program Could Save Millions," (ACN:06-40216), and that the actual prices charged to retail pharmacies were as much as 42% below "AWP." *See* Medicaid Action Transmittal No. 84-12 (Sept. 1984), *reprinted in* Medicare & Medicaid Guide (CCH) ¶ 34,157.

This 1984 OIG report audited drug prices in six states and concluded that "AWP" was not "even an adequate estimate of the prices providers are generally paying for their drugs. AWP represents a list price and does not reflect several types of discounts." The OIG recommended that Medicaid program policy and regulations be revised to require states "to abandon the AWP reimbursement

methodology" and adopt drug pricing systems that would more closely estimate the prices providers paid for pharmaceuticals.4/

State Medicaid officials could certainly have concluded that a 42% discount to a retail pharmacy suggested that even larger discounts from "AWP" were offered to providers with greater purchasing power. Indeed, they could hardly have reached any other conclusion from the OIG's findings. 5/

The published information that was available to State Medicaid officials about pharmaceutical pricing outside the retail pharmacy arena took a quantum leap with the August 1989 publication of the Senate Special Committee on Aging's Majority Staff Report entitled "Prescription Drug Prices: Are We Getting Our Money's Worth?" This document contains the following observations about the reimbursement system:

- "There are two markets in the U.S. for most big selling prescription drugs: a price competitive market characterized by deep discounts off the published list price, and a high-priced market, where retail

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4/ In 1989, the OIG again concluded that pharmacies were purchasing drugs at large discounts below "AWP," and recommended that "alternate reimbursement methods be studied and consideration be given to using a reimbursement method other than AWP or permit AWP to be appropriately discounted for reimbursement purposes." Report of DHHS, OIG, "Use of Average Wholesale Prices in Reimbursing Pharmacies Participating in Medicaid and the Medicare Prescription Drug Program," A-06-89-00037, *reprinted in* Medicare & Medicaid Guide (CCH) ¶38, 215.

5/ Texas, for example, stated in pleadings in 1985 that "AWP" was basically the suggested price for a drug and likened "AWP" to "the sticker price on a new car." "Thus, while claiming reimbursement using the AWP as a cost basis for the drug, the providers actually paid much less than the AWP." Decision No. 961, Department of Health and Human Services, Departmental Grant Appeals Board, Docket Nos. 87-137, 87-177, 88-09, 88-70.

customers, Medicare and Medicaid purchase their prescription drugs."

- "The VA achieves an average discount of *41% off AWP for single source drugs and 67% off AWP for multiple source drugs.*"
- "Hospitals, HMOs and nursing homes that contract with wholesalers *achieve discounts up to 99% off AWP.*"

(Emphasis added).

What did this publicly available report tell government officials about price discounting? First, "published list price" was subject to "deep discounts" for "most big selling prescription drugs" – in other words, published list prices (such as "WAC") were not necessarily the price at which providers actually bought pharmaceuticals.

Second, the Veterans' Administration ("VA") achieved *average* discounts of 41% off AWP for single source drugs and 67% for multiple source drugs. The report showed that manufacturers sold to the government *not* at "AWP" or even "AWP minus 15%," but at an *average* price of "AWP minus 41%" and "AWP minus 67%." It is worth noting that the Federal Supply Schedule from which the VA purchases pharmaceuticals was a matter of public record.

Third, providers with purchasing power (hospitals, HMOs, and nursing homes) were able to contract with *wholesalers* to purchase pharmaceuticals for discounts of up to "AWP minus 99%." This statement obviously shows that "AWP" did not represent acquisition cost for these providers.

In light of this information, States looking at the "WAC" published by the commercial pricing services could not reasonably have interpreted it to equal

provider acquisition cost. The conclusion is inescapable, for States knew that (i) providers could obtain pharmaceuticals for "deep discounts" of up to "AWP minus 99%" *and* (ii) the published "WAC" was not 99% less than "AWP." Once again, and still, "WAC" was generally understood to be the *undiscounted* price to wholesalers, not actual provider acquisition cost. 6/

4. Information Published During the 1990s Reinforced That "AWP" Did Not Equal Acquisition Cost and Expanded the Government's Knowledge to the Physician Market

By the 1990s, it was beyond question that "AWP" did not equal or approximate provider acquisition cost. HCFA repeatedly refused to permit states to reimburse Medicaid providers at AWP and disallowed matching funds to those that did. A published court decision and administrative decisions held that States could not rely on "AWP" in carrying out their responsibility to determine "Estimated Acquisition Cost" ("EAC") for pharmaceuticals.7/ HCFA also revised the State Medicaid Manual by specifically including an advisory to state Medicaid administrators that "AWP" exceeded actual acquisition cost and that it was not acceptable for a state plan to reimburse drug cost using "AWP" without factoring in

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6/ HCFA's senior officials obviously were aware of the substance of the Special Committee on Aging's Report; they told a U.S. Senate Committee in November of 1993 that: "[H]ospitals and health maintenance organizations are employing in-house formularies to negotiate effectively with pharmaceutical manufacturers for significant price discounts."

7/ *Louisiana v. United States Dep't of Health & Human Servs.*, 905 F.2d 877, 880 (5th Cir. 1990) ("Several commenters suggested that AWP would be a good measure, but the Secretary and SRS rejected this because 'AWP data are frequently inflated'") (quoting 40 Fed. Reg. 34,518 (Aug. 15, 1975)); *In re Arkansas Dept. of Human Servs.*, No. 1273 (HHS Dept. App. Bd. Aug. 22, 1991); *In re Oklahoma Dept. of Human Servs.*, No. 1271 (HHS Dept. App. Bd. Aug. 13, 1991).

a significant discount. "Medicaid Pharmacy - Actual Acquisition Cost of Generic Prescription Drug Products," Report of DHHS, OIG, Office of Audit Services, A-06-97-00011, *reprinted in* Medicare & Medicaid Guide (CCH) ¶ 45,559.

Given these rulings, States as a matter of law could not have "relied" on "AWP" to equal provider acquisition cost. To the contrary, HCFA had specifically and repeatedly told them *that it did not*.8/ States knew that to carry out their responsibility to determine "EAC," they had to determine a percentage *below* "AWP" at which to reimburse. Whether they used empirical methods to choose that amount – and what amount they chose – had nothing to do with the information the Manufacturers provided to the commercial pricing services.9/

_/ The GAO advised Maryland in 1993 that it was reimbursing retail pharmacies amounts that exceeded the actual purchase price by as much as 34%. *See* GAO, Medicaid: Outpatient Drug Costs and Reimbursements for Selected Pharmacies in Illinois and Maryland (Mar. 1993). In February 1997, the OIG found that Maryland pharmacies on average were paying 41.9% below "AWP" for generic drugs. Maryland responded by suggesting that HCFA link AWP to average manufacturer price as defined in the Medicaid rebate program. Report of DHHS, OIG, Office of Audit Services, "Review of Pharmacy Acquisition Costs for Drugs Reimbursed Under the Medicaid Prescription Drug Program of the Maryland Department of Health and Mental Hygiene," A-06-89-00037 (1996).

_/ In a 1991 administrative appeal, Arkansas argued that "AWP" represented the state's "best estimate of the price generally and currently paid for those drugs." The hearing board rejected that claim, finding: "[the] State *was aware* that pharmacies generally paid less than that amount and that ... the State had *no pertinent records to support a determination that AWP represented the price generally and currently paid.*" Docket No. 90-119, August 21, 1991 (emphasis added).

HCFA underscored the need for the States to use empirical methods in the fall of 1994, when it sent the Directors of State Medicaid Agencies a circular entitled "Expiration of Pharmacy Reimbursement Moratorium – INFORMATION." The circular reminded States that they would be able to adjust reimbursement rates for prescription drugs effective December 31, 1994 and reminded states that they should:

> [D]etermine that their estimated acquisition cost (EAC) levels are current. By definition, EAC means the agency's best estimate of the price generally and currently paid by providers for a drug marketed or sold by a particular manufacturer or labeler in the package size of drug most frequently purchased by providers. States wishing to modify their EAC levels may, among other methods of verification, audit an appropriate number of pharmacies to determine current acquisition costs before making modifications to the EAC levels. Additionally, States will also be able to expand or develop their own State maximum allowable cost program for multiple source drugs, as we do currently on the Federal Upper Limits (FUL) List.

The Manufacturers do not know what the States or HCFA did in response to this directive, but HCFA's February, 1998 description of its FY 1999 legislative proposals again stated that "AWP" "is but a 'sticker' price." These are the precise words the President had used months earlier in telling the nation that Medicare was paying too much for prescription drugs for reasons that "aren't even illegal."

HCFA concurred in the President's view that the conduct was legal. In November 1998, the HHS-OIG reported that "the published AWPs used in determining the Medicare allowed amounts for certain prescription drugs can be many times greater than the actual acquisition costs available in the marketplace." "Comparing Drug Reimbursement: Medicare and Department of Veterans Affairs,"

OEI-03-97-00293, at ii (Nov. 1998). Certainly this information came as no shock to HCFA. In fact, HCFA Administrator Nancy-Ann Min De Parle responded that under HHS' 1998 budget proposal, "physicians and suppliers who bill Medicare for outpatient drugs . . . would be paid their acquisition cost. This would have removed the mark-up currently being paid above the true market price." Thus, in HCFA's view, the gap between "AWP" and acquisition cost – for physicians and suppliers – was not some nefarious construct of the Manufacturers, but was simply a known mark-up.

The Department of Justice has hinged its arguments in this case on the contention that HCFA knew about the mark-up in the pharmacy market, but somehow did not realize the extent of the mark-up in other provider-administered tiers of the pharmaceutical market. The published information discussed above would be sufficient without more to dispose of that contention, but there is more. The data that the government reported during the 1990s lay the Department's position to rest.10/

In November 1991, HCFA responded to public comments on a proposed Medicare physician fee schedule for pharmaceuticals administered in physician offices. Although the Department of Justice has asserted in this case that "no one

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10/ There continued to be a wealth of information about the amount below "AWP" at which retail pharmacies purchased prescription drugs. For example, reports submitted by the National Association of Retail Druggists to Congress in 1992 showed that AWP for brand-name drugs could exceed the price paid by the provider by up to 94%. *See* Hearing Before the Subcomm. on Health and the Environment of the Comm. on Energy and Commerce for the House of Representatives (Jul. 31, 1992).

understood" the mark-up that physicians made on pharmaceuticals they administered, the alleged "lack of understanding" was not due to any lack of knowledge. Comments published in the Federal Register flatly stated that physicians could purchase many drugs for "*considerably less* than 85% of AWP." 56 Fed. Reg. 59,524 (Nov. 25, 1991)(emphasis added). Government officials must have recognized that even if they reimbursed at "AWP minus 15%" (and few states had reduced reimbursement to that level in 1991), physicians were getting a "considerable" mark-up on "many" drugs.

Published reports continued to evidence HCFA's understanding of discounts in the physician market. In 1992, the OIG compared the AWP and physicians' actual cost for commonly-used chemotherapy drugs and noted spreads of 12% to 83%. *See* DHHS, OIG Report, "Physicians' Costs for Chemotherapy Drugs, A-02-91-01049, at App. II and III (Nov. 1992), *reprinted in* Medicare & Medicaid Guide (CCH) ¶ 40,927. The report expressly found: "there is no single discount rate which can be applied to the AWP to provide a reasonably consistent estimate of the physician's acquisition cost." There is no basis for the government to argue that State Medicaid officials did not understand that physicians were obtaining a mark-up administering drugs when acquisition cost was as low as "AWP minus 83%" and reimbursement was typically "AWP minus 5%."

The OIG report also highlights – almost eight years ago and well before the qui tam involved here was filed – that information published by the

commercial pricing services was not intended to address the acquisition cost of drugs administered in physician offices:

> Red Book officials advised us that their data on AWPs, like the information used by the Blue Book or Medispan, is meant to approximate the cost to retailers (pharmacists) only. These officials also emphasized that their focus has always been the pharmacy sector which is their chief market *and that this is clearly understood by those who supply information to the Red Book.*

Id. at ¶ 33,792 (emphasis added). Thus, in 1994, the OIG recognized that the Manufacturers "clearly understood" that the information they supplied to the commercial pricing services related to pricing to retail pharmacies. The Department of Justice's attempt to suggest otherwise in this case is a wholesale rewriting of history.

It is not even necessary to analyze the many government reports pointing out that "AWP" did not equal provider acquisition cost. The following widely available characterizations of "AWP" are sufficient to prove that the government long knew the difference.

- The HEW Report cited above described "AWP" as "an umbrella under which prices are discounted rather than reflecting actual prices." (1968)
- The Medicaid Bureau of HCFA referred to "AWP," "which was a realistic catalogue price in 1970, but which now is an arbitrary price, based on the Red Book." (October 1977)
- The Office of Inspector General described "AWP" as "non-discounted list price." (1984)
- The General Accounting Office defined "AWP" as "the price pharmacies would pay if they did not receive discounts from manufacturers." (March 1993)

- The Congressional Budget Office defined "AWP" as "the published (list) price that manufacturers suggest wholesalers charge their customers." (January 1996)

- The Inspector General of the Department of Health and Human Services referred to "AWP" as "recommended by manufacturers but do not accurately reflect actual wholesale prices." (1997)

- The HCFA Medicare and Medicaid Guide referred to "AWP" as "not a true discounted price and, therefore, does not reflect the cost to the physician or supplier furnishing the drug to the Medicare beneficiary." (Jan. 1998)

- The Office of Inspector General referred to "AWP" as "generally inflated over actual acquisition costs." (Oct. 1998)

5. The States Knew That Changing to a "WAC"-Based Reimbursement System Would Not Equate to Paying Provider Acquisition Cost

It is no answer to say that states "responded" to their knowledge by shifting to "WAC"-based reimbursement. In the first place, even the alleged "WAC" states have made it clear that they have *not* intended to reimburse at provider acquisition cost. 11/

11/ For example, when the OIG criticized Florida for excessive reimbursement to pharmacies, State Medicaid officials responded:

> Comparing acquisition costs for Florida pharmacies to AWP, as an academic exercise, proves that pharmacies, like almost all retail businesses, purchase goods at some discount below suggested list prices, but does not provide an indication of need to change current reimbursement policy.... *Restricting reimbursement to actual cost might have the unintended effect of discouraging purchase of promotional products and eventually shifting the market to single-source products which are universally much more costly.*

DHHS, OIG Report, "Review of Pharmacy Acquisition Costs for Drugs Reimbursed Under the Medicaid Prescription Drug Program for the Florida Agency for Health Care Administration," A-06-95-00065, at Appendix 4 (Aug. 1996)(emphasis added).

Second, "WAC" as defined by the States was at best a fluid concept. States that allegedly reimbursed at "WAC" never defined "wholesaler" or indicated what transactions should be considered in determining "WAC."12/ It was clear by 1996 that some states used "WAC" as the initial basis for estimating EAC in the retail pharmacy setting, but felt free to modify "WAC" as they deemed necessary. States had made clear that they had varying definitions and methods of obtaining "WAC" data. "Appropriateness of Medicare Drug Prescription Allowance," OIG Rept. No. OEI-03-95-00420, at 9 & App. B (May 1996). 13/

However States may have defined the term, it is clear that the rest of the world always viewed "WAC" as an undiscounted price to wholesalers. Judge Sporkin made this express finding in *FTC v. Cardinal Health Inc.*, 12 F. Supp. 2d 34, 40-41 (D.D.C. 1998): "WAC" is "a wholesale list price ... wholesalers can often acquire the drugs for prices less than the listed WAC." The following widely available characterizations of "WAC" further demonstrate this point.

See also Report of DHHS, OIG, Office of Audit Services, A-06-95-00072 (1996)(Virginia observes "acquisition cost is just one factor involved in pharmacy reimbursement policy"); *supra* note 10 (Arkansas argued for reimbursement to pharmacies at "AWP" even though State officials were aware "that pharmacies generally paid less than that amount").

__/ The Department of Justice has used this lack of definition as a license to argue in this case that entities not typically understood to be wholesalers "should be" in the undefined "wholesaler" category. Like so much of the rest of the Department's case, this argument is at odds with the historical record.

__/ Alabama, for example, reported in 1996 that it determined "WAC" information through a survey of "local wholesalers."

- The National Wholesale Druggists' Association defined "WAC" as "the published price the wholesaler pays to the manufacturer for a product." (1995)

- Medi-Span called the "WAC" "the estimated cost to the wholesaler by the drug manufacturer.... Actual values can vary from these estimated values as wholesalers experience discounts ...." (June 1995)

And the States – despite their current Captain Renault-esque 14/ claims of ignorance – knew this. On April 4, 1997, the Chief of the Division of Quality Assurance for the Maryland Department of Health and Mental Hygiene wrote the Director of the Medical Care and Compliance Administration:

> *As a result of miscellaneous knowledge gathered over time, Program staff (MCFCA, PSOA, MCPA) has often asserted that the Maryland Medical Assistance reimbursement for pharmaceuticals, currently at wholesale acquisition cost plus 10% (WAC + 10) far exceeds the true acquisition cost to the Pharmacy.* This opinion holds consistent whether the pharmacy is retail, home IV, nursing home, or hospital.

(Emphasis added).15/

__/ Renault: "I am shocked, shocked to find gambling going on in here."
Croupier: "Your winnings, sir."
Renault: "Oh, thank you very much."

Casablanca (Warner Bros. 1942), available at http://members.aol.com/VladW/casabla.pdf, at 94.

__/ Furthermore, since at least 1988, Maryland regulations have provided that physicians shall "charge the Program [their] actual acquisition cost for the drugs dispensed." COMAR § 10.09.03.07G. The Manufacturers cannot know whether Maryland compared this data on actual acquisition cost to "WAC." They know, however, that Maryland officials did nothing to change the reimbursement formula for pharmacies and other providers.

6. Conclusion

Because they have not conducted discovery, the Manufacturers do not know what the States did in response to this vast amount of information that "AWP" and "WAC" did not approximate provider acquisition cost. The Manufacturers also do not know what the States did in response to HCFA's directive that they take steps to assure that their EACs were current and not dependent on published "AWPs." It is clear, however, that state officials' claims of "we didn't know" or "we couldn't find out" that "AWP" and "WAC" substantially exceeded provider acquisition cost are wholly undermined by the public record.

The record shows that HCFA and HHS – who are responsible for the federal portion of the Medicaid program – knew about these pricing issues. The record further shows that the States were informed about the issues through communications from HCFA and a vast amount of other publicly available information. Their own agencies were very much aware of the large discounts available from pharmaceutical manufacturers.16/ The States did not lack knowledge of these facts; they simply made the policy determination not to make changes.17/

__/ The states could have learned from their constituent agencies that "state and local government entities . . . have been able to purchase drugs at significantly discounted prices.... In addition, public hospitals have obtained significant discounts off retail and wholesale prices for both outpatient and inpatient drugs by using large group purchasing organizations to negotiate with drug manufacturers." "Drug Prices: Effects of Opening Federal Supply Schedule for Pharmaceuticals Are Uncertain," GAO/HEHS-97-60 (June 11, 1997).

__/ For example, in 1984 the Director of the Arkansas State Medicaid Agency advised the state legislature "that his agency will change its current system and

B. There Was No Standard or Widely-Accepted Definition of the Pricing Terms

The government has conceded in our discussions that there has never been a statutory, regulatory, or accepted industry standard definition of "AWP" or "WAC." At the same time, however, government attorneys have insisted that somehow "everyone" knew what these terms "meant."

Even a cursory review of the characterizations of "AWP" and "WAC" shows that they were "non-standard," inconsistent and sometimes contradictory.

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base drug reimbursement on the actual costs paid by pharmacies rather than AWP. He further advised that this action ...should be done by the end of March 1984 ...." *See* Medicare & Medicaid Guide (CCH) ¶ 34,157. Yet in 1991, Arkansas was still arguing that "AWP" represented the state's best estimate of acquisition cost. *See supra* note 9. The Arkansas example points out that knowledge of the disconnect between "AWP" and "actual [provider] costs" did not equate to action to change reimbursement methodology.

We understand that the government asserts that the Manufacturers somehow "concealed" the chargeback system from State and federal regulators. This contention flies in the face of the evidence and common sense.

The chargeback system has been widely practiced in the pharmaceutical industry for years. It has long been part of the public record. *See, e.g., In re Brand Name Prescription Drug Antitrust Litigation*, 186 F.3d at 784 (describing origin and operation of chargeback system).

It is inconceivable that state Medicaid regulators have been unaware of the chargeback system. Certainly, the federal government was expressly aware of it. *See. e.g.,* Testimony of Sarah F. Jaggar, Director Health Services Quality and Public Health, Health Education and Human Services Division, before the Subcommittee of Oversight and Investigations, Committee on Commerce, House of Representatives (Sept. 19, 1996). Given the congressionally mandated oversight responsibilities of the federal administrators, if HCFA felt that "chargebacks" were relevant to Medicaid reimbursement, it would have forwarded appropriate revisions of the State Medicaid Manual to the state Medicaid agencies.

1. Characterizations of "AWP" Were Not Uniform

The following characterizations of "AWP" demonstrate the lack of uniformity among the commercial pricing services, commentators, and government in assigning a meaning to the term.

- The Office of Inspector General characterized "AWP" as "the non-discounted list price." (1984)
- The Red Book advised the OIG that "AWP" was determined using algorithms that weighted various pricing information and general information concerning distribution channels (1992)
- The General Accounting Office characterized "AWP" as "the average of the list prices [that wholesalers charge pharmacies], collected from many wholesalers." (January 1993)
- The General Accounting Office characterized "AWP" as "the price pharmacies would pay if they did not receive discounts from manufacturers." (March 1993)
- The Congressional Budget Office characterized "AWP" as "the published (list) price that manufacturers suggest wholesalers charge their customers." (January 1996)
- Medi-Span characterized "AWP" as "(1) The suggested wholesale price to the retailer as given by the manufacturer [or] (2) The common wholesale selling price to the retailer as determined from a review of up to 15 wholesalers across the United States." (February 1996)

2. Characterizations of "WAC" Were Inconsistent

The following characterizations of "WAC" demonstrate the lack of consistency among the commercial pricing services, commentators, and federal and state governments in assigning a meaning to the term.

- The Red Book characterized "WAC" as "the manufacturer's quoted list price to wholesale distributors and [the WAC] does not reflect any deal terms or specialized contract pricing."

- First DataBank characterized "WAC" as "price to wholesaler or distributor."
- The General Accounting Office characterized "WAC" as "factory prices to the undiscounted market segment from manufacturers." (Jan. 1994)
- Colorado characterized "WAC" as "Direct Price plus 18%." (1996).
- Maryland characterized "WAC" as the price charged by pharmaceutical manufacturers and distributors who provide retail and institutional pharmacies with products used in filling prescriptions. (1991).

These characterizations are not uniform, but the common theme among them is that "WAC" is an *undiscounted* list price. None of the characterizations suggests that "WAC" equals or approximates actual acquisition cost.

C. The Government Cannot Prove the Essential Elements of an FCA Claim

1. The Government Cannot Prove "Falsity"

The absence of clear and consistent definitions of "AWP" and "WAC" means that the government cannot meet its burden of proving that the information the Manufacturers provided to commercial pricing services was "false or fraudulent." The government will have the burden of proving that its interpretation of these terms is correct and disproving any other. *See United States ex rel. Luckey v. Baxter Healthcare Corp.*, 2 F. Supp. 2d 1034, 1049 & n.9 (N.D. Ill. 1998)(government's burden to prove that ambiguous terms at issue are not subject to *any* other reasonable interpretation), *aff'd*, 183 F.3d 730 (7th Cir.), *cert. denied*, 120 S Ct. 562 (1999). Absent some express definition of the disputed terms in the manner that the government contends is proper, a court will not find a statement to

be "false." *Hagood v. Sonoma County Water Agency ("Hagood II")*, 81 F.3d 1465, 1477 (9th Cir.) ("How precise and how current the [submission at issue] needed to be in light of the statute's imprecise and discretionary language was a disputed question within the [government agency, and therefore the plaintiff's] evidence shows only a disputed legal issue; that is not enough to support a reasonable inference that the allocation was false within the meaning of the False Claims Act."), *cert. denied*, 117 S. Ct. 175 (1996); *United States ex rel. Weinberger v. Equifax, Inc.*, 557 F.2d 456, 461 (5th Cir. 1977), *cert. denied*, 434 U.S. 1035 (1978).

The difficulty in proving "falsity" where terms are not precisely defined is demonstrated by *United States ex rel. Cox v. Iowa Health Sys.*, 29 F. Supp. 2d 1022 (S.D. Iowa 1998). In *Cox*, the court considered the validity of an FCA case alleging that the defendants submitted false claims for air ambulance mileage reimbursement because they used "statute miles" rather than "nautical miles." The court found that the relator had failed to state a claim under the FCA, because the relator could not:

> [I]dentify any law, regulation, or other source suggesting federal medical programs expected air ambulance mileage claims to be in nautical miles rather than statute miles. In fact, relator describes the conversion practice in his complaint as "the standard, but carefully concealed, practice in the industry." *A standard billing practice within an industry could hardly be said to be false, when no controlling authority requires parties to submit claims in nautical rather than statute miles.*

Cox, 29 F. Supp. 2d at 1026 (citation omitted; emphasis added). In other words, absent some established definition of the term "miles," converting "nautical miles"

to "statute miles" and submitting reimbursement for "statute miles" was not false. 18/

It is apparent that "miles" is more readily defined than "AWP" or "WAC." Yet the court found that a provider that chose a reasonable interpretation of "miles" did not file a false claim, particularly stressing that the defendant's practice was "standard . . . within the industry." Neither the commercial pricing services' definitions nor "law, regulation or other source" provide a consistent – much less a controlling – definition of "WAC" or "AWP." Hence, so long as the information the Manufacturers provided to the commercial pricing services was consistent with existing understanding of the terms, it could not have been false.

The government apparently contends that *United States ex rel. Oliver v. Parsons Co.*, 184 F.3d 1101, 1105 (9th Cir. 1999), compels a different conclusion. In *Oliver*, the court of appeals distinguished *Hagood II*, holding that it applied only in cases where the regulations with which the defendant was attempting to comply were "discretionary."

> Unlike *Hagood*, this case involves regulations that, while unquestionably technical and complex, are not discretionary. Their meaning is ultimately the subject of judicial interpretation, and it is [defendant's] compliance with these regulations, as interpreted by this court, that determines whether its accounting practices resulted in the submission of a "false claim" under the Act.

__/ The principle enunciated in *Cox* – that a reasonable interpretation of an ambiguous term negates falsity – is well established. *See Luckey*, 2 F. Supp. 2d at 1049 ("ambiguous statutory requirements, where no regulations further define those requirements, cannot hold a defendant to the government's strict interpretation, so long as defendant's interpretation was reasonable"); *United States v. Napco Int'l, Inc.*, 835 F. Supp. 493, 497-98 (D. Minn. 1993) (no false statement where regulations did not adequately define requirements).

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Oliver is simply not relevant here. There are no regulations at issue in this case at all; certainly the government has conceded that there are no regulations defining "AWP" or "WAC." Indeed, on rehearing, the Ninth Circuit took pains to point out that its decision applied only to "interpretation of a federal regulation," not interpretation of a contract, an agency directive, or scientific judgment. *United States ex rel Oliver v. Parsons Co.*, 195 F.3d 457, 460 (9th Cir. 1999), *petition for cert. filed*, No. 99-1225 (U.S. Jan, 20, 2000).

Here, in fact, the government has during our discussions suggested to the Manufacturers that they should have provided as their "WAC" the "actual" or "average" sales price of the product (although the government has not advised the Manufacturers how that figure should have been calculated), the Average Manufacturer Price ("AMP") as defined by the Medicaid rebate statute, the price net of discounts, or the contract or other price to specialty distributors.19/ It is telling that the government is itself unable to provide a consistent or meaningful definition

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__/ The Fiscal Year 2001 budget submitted by HHS proposes that the Secretary be allowed to make the AMP available to the States "so that the States can use this data to accurately set Medicaid drug reimbursement rates." FY 2001 Budget, at 71. This proposal is ironic given that the legislative history of the Medicaid rebate statute clearly states that "AMP" and "Best Price" are to be made available to state agencies on request. H. R. Conf. Rep. No. 964, 101st Cong., 2d Sess. 823, *reprinted in* 1990 U.S.C.C.A.N. 2374, 2523. HCFA decided not to make the information available. 60 Fed. Reg. 48,474 (Sept. 19, 1995).

Nevertheless, if HHS agreed with the Department of Justice's view that the "WAC" that the Manufacturers were to report to the commercial pricing services was to equal "AMP," its current proposal would obviously be unnecessary.

of "WAC;" it is undisputed that the government has identified nothing that would have told the Manufacturers that any or all of these definitions were in force. 20/

It is fanciful for the government to assert that the Manufacturers simply "should have known" to report one or all of these prices as "WAC." There was no notice to the Manufacturers what the government expected. There were no regulations to guide their conduct, such as the defendant had available in *Oliver*. There was, indeed, no consistent guidance, so the government will not be able to prove that the Manufacturers acted unreasonably, much less fraudulently. The point could hardly be made more clearly than by the words of the *Oliver* court:

2. The Government Cannot Prove the Manufacturers Acted "Knowing" of "Falsity"

Nor can the government prove that the Manufacturers "knowingly" provided "false" information. The FCA defines "knowing" and "knowingly":

> For purposes of this section, the terms "knowing" and "knowingly" mean that a person, with respect to information—
>
> (1) has actual knowledge of the information;

20/ The Department of Justice has attempted to invent a "standard" by citing a 1994 OIG report indicating that retail pharmacies on average paid 16% below "AWP" for prescription drugs. From that bit of information (irrelevant to the non-pharmacy market), the government asserts that "everyone knew" that "WAC" was "supposed to" equal "AWP minus 16%." In reaching this conclusion, the government ignores that an "average" by definition means that there was a range above and below 16 percent. It also ignores the wealth of information discussed in the text that demonstrates, beyond dispute, that there was no standard.

(2) acts in deliberate ignorance of the truth or falsity of the information; or

(3) acts in reckless disregard of the truth or falsity of the information,

and no proof of specific intent to defraud is required.

31 U.S.C. § 3729(b).

We have demonstrated above that the government will be unable to prove that the information the Manufacturers submitted was "false." The government's case will also founder on the requirement that it prove that the Manufacturers knew, demonstrated deliberate indifference to, or recklessly disregarded a risk that they were supplying incorrect or misleading information. *See, e.g., United States ex rel. Hochman v. Nackman*, 145 F.3d 1069, 1074-75 (9th Cir. 1998) ("Absent evidence that the defendants knew that the VHA Guidelines on which they relied did not apply, or that the defendants were deliberately indifferent to or recklessly disregardful [sic] of the alleged inapplicability of those provisions, no False Claims Act liability can be found"); *Hagood v. Sonoma County Water Agency*, 929 F.2d 1416, 1421 (9th Cir. 1991)), *cert. denied*, 516 U.S. 1114 (1996); *United States ex rel. Lamers v. City of Green Bay*, 998 F. Supp. 971, 986 (E.D. Wis. 1998), *aff'd*, 168 F.3d 1013 (7th Cir. 1999); *United States ex rel. Rueter v. Sparks*, 939 F. Supp. 636, 638-39 (C.D. Ill. 1996), *aff'd*, 111 F.3d 133 (7th Cir. 1997); *United States v. Napco Int'l, Inc.*, 835 F. Supp. 493, 497 (D. Minn. 1993).

In *United States v. Data Translation, Inc.*, 984 F.2d 1256, 1259 (1st Cir. 1992) (Breyer, J.), the First Circuit refused to find the defendant liable under

the FCA for providing "false" pricing information. The court found that the form in question was "virtually unintelligible" and could not reasonably be interpreted to require disclosures beyond those the defendant made. *Data Translation* is particularly relevant here because the Texas Medicaid Formulary Application (on which the government has placed heavy reliance) contains the following terms: "Average of suggested wholesale price to pharmacy," "Price to wholesaler and/or distributor," "Special price to chain warehouse," "Special price to institutional pharmacy," "Direct price to pharmacy," and "Other price." There were no definitions of these terms provided by Texas and the form is indistinguishable from the one at issue in *Data Translation*.

And *Oliver* – a case on which the government has heavily relied – unequivocally holds that the government cannot prove knowledge on these facts:

> A contractor relying on a good faith interpretation of a regulation is not subject to liability, not because his or her interpretation was correct or "reasonable" but *because the good faith nature of his or her action forecloses the possibility that the scienter requirement is met.*

195 F.3d at 460 (emphasis added). 21/

__/ *See also United States v. Hill*, 676 F. Supp. 1158, 1171 (N.D. Fla. 1987)(rejecting "knew or had reason to know" standard of liability); *Commercial Contractors, Inc. v. United States*, 154 F.3d 1357, 1366 (Fed. Cir. 1998) (issue is whether the contractor's asserted interpretation is so plainly lacking in merit that the requisite state of mind can be inferred; if contractor submits a claim based on a plausible but erroneous contract interpretation, the contractor will not be liable, absent some specific evidence of knowledge that the claim is false); *Nackman*, 145 F.3d at 1075 (no FCA liability when defendants believed, based on "at least superficially plausible" contract interpretation, that they were entitled to specialty pay for a physician's salary under the VHA Guidelines).

In this case, the pricing information the Manufacturers provided at the request of the commercial pricing services differs from the hindsightful interpretation of "what they should have submitted" now being pressed by the government. But the descriptions of the terms contained in the commercial pricing services were inconsistent and, of course, none of them remotely resembled the definition the government now seems to be advancing. The government's attempt to prove that the Manufacturers "knowingly" submitted "false" information by failing to report provider acquisition cost – which the Manufacturers were never asked to report – will fail.22/

3. The Government Cannot Prove that it Justifiably Relied on the Manufacturers' Statements

Courts have long recognized that there must be a close nexus between the false statement or conduct and the resulting false claim. In *United States v. Veneziale*, 268 F.2d 504, 505 (3d Cir. 1959), for example, in determining whether a vendor's false statements on a loan application "caused" the resulting false claim, the court indicated that reliance was necessary under the FCA:

> [I]t is clear that the fraudulent statement in the loan application as to the purpose of the borrowing was an essential inducement to the Federal Housing

_/ Courts have held that a defendant who files a claim acting under a "reasonable" mistake does not act "knowingly." This is so because a mistake that is "reasonable," "innocent," or even one that rises to "simple" negligence does not satisfy the scienter requirement of the FCA, which requires at a minimum that one demonstrate "reckless disregard" regarding the truth or falsity of the statement or claim. *Hindo v. University of Health Sciences*, 65 F.3d 608, 613 (7th Cir. 1995) ("innocent mistakes or negligence are not actionable under this section") (citing *Wang v. FMC Corp.*, 975 F.2d 1412, 1420 (9th Cir. 1992) and *Hagood I*, 929 F.2d at 1421)).

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> Administration guaranty upon which the government has now had to pay. *Thus the wrong of the defendant was an important, even an essential factor in subjecting the government to an enforceable demand for money.*

(Emphasis added).

Indeed, a Florida district court held that a criminal false statement conviction did not collaterally estop the defendants in a later civil false claims suit because the criminal case did not require the government to prove reliance:

> In a prosecution for making a false statement under Title 18, United States Code, Section 1001, proof of the agency's reliance on the statements is not necessary to sustain a conviction. The cases discussing the element of reliance under the False Claims Act do not address whether this requirement finds its roots in the statute or in some common law elements of fraud. I prefer to base the requirement of reliance in the language of the False Claims Act itself, as well as on common sense. In order for a false statement in a guaranty application to "cause" the submission of a false claim (i.e., the eventual demand for payment on the guaranty), the Government would certainly need to prove that it relied on a false statement in issuing the guaranty in the sense that, but for the false statement, it would not have issued the guaranty. In the absence of reliance on the false statement, it is difficult to see how the defendant's false statement could have "caused" the false claim. It must be noted that this issue of reliance differs from the issue of reliance and causation relating to the Government's sustained damages.

United States v. Hill, 676 F. Supp. at 1158, 1176 n.25.

As the last sentence of the passage quoted above makes clear, courts have also repeatedly recognized that to establish damages under the FCA, the government must also establish that the false statement caused the government's damages. *E.g.*, *United States v. Miller*, 645 F.2d 473, 475-76 (5th Cir. 1981); *United*

States v. Hibbs, 568 F.2d 347, 352 (3d Cir. 1977); *see also United States v. First Nat'l Bank*, 957 F.2d 1362, 1366 n.4 (7th Cir. 1992). The widely accepted standard for damages reliance is that the false statements directly caused the government's loss. *United States v. Hibbs*, 568 F.2d 347 (3d Cir. 1977). The former Fifth Circuit adopted the direct-cause standard for damages reliance in *Miller*, 645 F.2d at 475-76, holding: "[t]he language of the statute clearly requires that before the United States may recover double damages, it must demonstrate the element of causation between the false statement and the loss. In the context of a federal housing case, the United States must show that the false statements in the application were the cause of the subsequent defaults." 23/

The government must also prove that reliance on the "false statements" in question was justified. In *Data Translation*, the court held that false statements provided to the government regarding the defendant's pricing, which the government claimed resulted in its paying more for the defendant's computer boards, could not support an FCA action. The court determined that even if the defendant provided false information, the government employee's "negligence in relying upon such a statement, not the statement itself, would have been the predominant cause of any resulting higher price." Of critical importance to this case, the court found that the government representative had information in his possession revealing that the defendant's false statements "made little sense." The

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23/ In 1986, Congress proposed liberalizing the *Hibbs* standard and allowing recovery if the government showed that the false statements were the "but for"

"false" information could not support an FCA claim because the government was unjustified as a matter of law in relying on the information. *Data Translation*, 984 F.2d at 1266.

The evidence demonstrates that for more than a decade, HCFA has not relied – and has told the States that they could not rely – on the pricing information set out in the commercial pricing services. The federal and state governments have long known that information published in the commercial pricing services was never meant to address pricing to providers other than retail pharmacies, and have long known of the disparity between "AWP," "WAC," and provider acquisition cost. It is well-settled that inaction on the part of the government despite its knowledge of the underlying facts demonstrates lack of reliance as a matter of law. 24/

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cause of the government's damages. The proposal was rejected. S. Rep. No. 345, 99th Cong. 2d Sess. 20, *reprinted in* 1986 U.S.C.C.A.N. at 5285.

__/ An early post-amendment case held that government knowledge negated the element of falsity. *See Boisjoly v. Morton Thiokol, Inc.*, 706 F. Supp. 795, 809 (D. Utah 1988) ("Because FCA liability requires an element of fraud or falsity, courts have disallowed FCA claims where the Government knew, or was in possession at the time of the claim, of the facts that make the claim false"). Although this seems to us (and the commentators) a sounder view of the effect of the defense, later cases have focused on the intent element. See BOESE, *supra*, at II; Neal J. Wilson, The Government Knowledge "Defense" to Civil False Claims Actions, 24 Pub. Cont. L.J. 43, 51-55 (1994).

The government knowledge defense predates the 1986 FCA amendments, but courts have continued to recognize that government knowledge negates the intent necessary to support an FCA claim. The leading case is *United States ex rel. Hagood v. Sonoma County Water Agency ("Hagood I")*, 929 F.2d 1416 (9th Cir. 1991), but there are a large number of decisions precluding liability based on government knowledge. *See Butler*, 71 F.3d at 327 ("[w]e examine the individual statements below, to determine whether, if they are arguably false, the government's knowledge of their deficiencies negates [defendant's] intent"); *Wang v. FMC Corp.*, 975 F.2d 1412, 1421 (9th Cir. 1992); *United States ex rel. Kreindler &*

Courts look to the extent and nature of the government's knowledge to determine whether the defendant had the requisite intent. The critical inquiry is *not* whether the government had "all the facts," but whether it was in possession of *sufficient* facts to know or understand the true nature of the claim submitted to it. In *Lamers*, the court rejected the precise argument that the government knowledge defense was inapplicable because the government did not know *all* of the relevant facts when it made its funding decision. The court held that the government had sufficient facts – including those it received from sources *other than the defendant* – to preclude an FCA claim. The court's reasoning in *Lamers* is compelling; the

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Kreindler v. United Techs. Corp., 985 F.2d 1148, 1156-57 (2d Cir.) ("government knowledge may be relevant to a defendant's liability" in that it may support a finding that the defendant lacked the requisite intent), *cert. denied*, 508 U.S. 973 (1993); *Lamers*, 998 F. Supp. at 988 ("no violation exists where the government has not been deceived"); *United States ex rel. Durcholz v. FKW Inc.*, 997 F. Supp. 1159, 1167 (S.D. Ind. 1998), *aff'd*, 189 F.3d 542 (7th Cir. 1999); *United States v. Frierson*, No. 95 C 503, 1997 WL 136280, at *13 (N.D. Ill. Mar. 20, 1997) ("A reasonable jury could find that the [government's] approval of the two claims in question could affect [defendant's] belief that the expenses were proper"); *United States ex rel. Milam v. Regents of the Univ. of Cal.*, 912 F. Supp. 868, 888-889 (D. Md. 1995) (government's knowledge of the problems with the research "'may be relevant to a defendant's liability'") (quoting *Kriendler & Kriendler*, 985 F.2d at 1156-57)).

United States v. Robbins, 207 F. Supp. 799, 807 (D. Kan. 1962), is particularly apt here. In that case, the court held that the defendants' false statements made to county representatives to seek approval for an emergency disaster relief program were not actionable under the FCA because the federal government relied in paying the claims on the county's determinations that eligibility requirements had been met, not on the false statements. The court found that county representatives were "well acquainted" with the factual circumstances that were "misrepresented" in the application.

evidence that the government had "sufficient" facts to know that "AWP" and "WAC" did not equal or approximate provider acquisition cost is overwhelming. 25/

CONCLUSION

Setting Medicaid reimbursement for drugs is the responsibility of the State Medicaid agencies, subject to federal oversight. If the state agencies made "overpayments," it was not because the Manufacturers "knowingly" made "false statements." It was because – despite their knowledge of the facts set out in this Analysis – the state agencies made an affirmative decision to do so. And HCFA – despite its knowledge of those same facts – approved these reimbursement regimes.

In light of the evidence detailed above, the principles set forth in the "Guidance on the Use of the False Claims Act in Civil Health Care Matters" counsel against intervening in this case. The Guidance compels careful evaluation whether a potential defendant "knowingly" engaged in false or fraudulent conduct, taking into account such factors as "notice to provider" and "clarity of the rule/policy." A careful review of those factors demonstrates that the Department of Justice should not pursue this case.

25/ Nor does the "fraudulent course of conduct" theory assist the government. Whatever its merits, the fraudulent course of conduct theory has incontrovertibly been rejected in the Eleventh Circuit. United States ex rel. Weinberger v. Equifax, Inc., 557 F.2d 456 (5th Cir. 1977), *cert. denied*, 434 U.S. 918 (1978). Even if the theory were to be accepted by the Eleventh Circuit, the "fraudulent course of conduct" cases all involve facially true claims "rendered false" by an initial lie or misrepresentation. *See, e.g., Harrison v. Westinghouse Savannah River Co.*, 176 F.3d 776, 786-87 (4th Cir. 1999); *United States v. Incorporated Village of Island Park*, 888 F. Supp. 419, 439-40 (E.D.N.Y. 1995). In fact, in the cases that adopt the theory, the defendant has uniformly violated a clear standard of conduct, knowing that its actions were wrong and, often, illegal. Here, the Manufacturers violated no clear standard and made no misrepresentation.

What the Department of Justice attacks as "overpayments" are in fact payments based on the balancing of a variety of competing policies, including provider network adequacy, ability of small pharmacies to make a profit, and political considerations.26/ The states did not rely, much less justifiably rely, on the Manufacturers in making those political and policy decisions. The FCA was not meant to be invoked in cases such as this, where government agencies made informed decisions with which the Department of Justice now disagrees.

We hope that this Analysis is helpful and look forward to discussing it with you if you have any questions, comments, or unresolved concerns.

26/ C. Robin Britt, Sr., Secretary of the North Carolina Department of Human Resources, expressed this point in his July 1, 1996 correspondence to the OIG: "We have recognized the problems that arise from balancing the appropriate EAC against assuring adequate access to providers by the recipient." DHHS, OIG report, "Review of Pharmacy Acquisition Costs for Drugs Reimbursed Under the Medicaid Prescription Drug Program of the North Carolina Department of Human Services," A-06-95-00071, at Appendix 4 (Sept. 1996). One such concern may be the protection of smaller "mom and pop" pharmacies who may not be able to negotiate large discounts from "AWP." *See Florida Pharmacy Association v. Cook*, 1998 WL 601108 (N.D. Fla. 1998)(rates must be "consistent with efficiency, economy, and quality of care" and "sufficient to enlist enough providers so that care and services are as available to Medicaid patients as to the general population in the geographic area").

Congress' response to the publicly-available information about the disparity between "AWP," "WAC," and acquisition cost is most telling. Congress first reacted to this wealth of information not by *lowering* Medicaid prescription drug reimbursement, but by *preventing the States from doing so.* The Omnibus Budget Reconciliation Act of 1990 *imposed a four-year moratorium on any reduction in drug reimbursement either by the federal government or a state.* 42 U.S.C. §1396r-8(f)(1). Furthermore, HCFA's administrator pointed out to the Inspector General that the President's FY 1998 budget proposed that physicians and suppliers be paid acquisition cost for outpatient drugs. "Congress did not enact our recommendation." Memorandum from N. DeParle to J. Brown (Oct. 28, 1998).